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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO.            | CONFIRMATION NO. |
|---|-------------|-------------------------|--------------------------------|------------------|
| 10/775,775  | 02/09/2004  | Clifford Eugene Gammons | 27455.00                       | 9324             |
| 22465   | 7590        | 10/19/2006              |                                |                  |
| PITTS AND BRITTIAN P C<br>P O BOX 51295<br>KNOXVILLE, TN 37950-1295 |             |                         | EXAMINER<br>BOUCHELLE, LAURA A |                  |
|   |             |                         | ART UNIT<br>3763               | PAPER NUMBER     |

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/775,775

Applicant(s)

GAMMONS, CLIFFORD EUGENE

Examiner

Laura A. Bouchelle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/9/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cianci et al (US 4140127). Cianci discloses a catheter sheath having a first panel member 48a and a second panel member 48b defining a tubular configuration, the first panel being folded over to form a double thickness, and the second panel being folded over to form a double thickness (Col. 3, lines 30-40). See Fig. 2. Cianci inherently discloses the steps of providing a first panel 28a and a second panel 28b and folding the panels and heat sealing the panels to each other. The claim 1 limitation of folding the panels prior to securement is considered to be a product by process limitation. These claims are not limited to the manipulations of the recited steps, only the structure implied but the steps. The patentability of a product does not depend on its method of production. See MPEP 2113.

### Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Barnes et al (US 3812769). Claim 13 differs from the teachings of Cianci in calling for the step of folding the first and second panels before securing the members together. Barnes teaches a method of manufacturing a two ply bag including the steps of first folding the first and second panels then sealing them together (Col. 1, line 65- Col. 2, line 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Cianci to include folding the panels before securing them as taught by Barnes as a low cost and efficient way to make a two-ply member.

5. Claims 2 and 3, and 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Wu et al (US 4246909) or Cianci in view of Barnes in view of Wu. Claim 2 differs from Cianci in calling for the cover to further comprise a throat. Claim 3 differs in calling for the width of the throat to be less than one half of the circumference of the medical probe. Claims 14 and 15 differ in calling for the step of providing a throat with the specified circumference. Wu teaches a cover 10 for a medical probe having a throat 37 that has been heat sealed with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

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6. Claims 4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Wu or Cianci in view of Barnes in view of Wu as applied to claims 2 and 13 above, and further in view of Poncy (US 4165000). Claim 4 differs from Cianci in view of Wu in calling for the first end of the cover to define a funnel configuration. Claim 16 differs in calling for the step of defining the funnel. Poncy teaches a medical probe cover having a first end with a flaring or funnel configuration defined by a heat sealing die to facilitate the insertion of the medical probe (Col. 4, lines 18-22). See Fig. 5. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to have a first end with a funnel configuration as taught by Poncy to facilitate insertion of the probe.

7. Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Poncy or Cianci in view of Barnes in view of Poncy. Claim 5 differs from Cianci in calling for the first panel member to extend beyond the second panel. Claim 17 differs in calling for the step of defining the extended portion. Poncy teaches a cover having a first panel 24 that projects beyond the end of the second panel 22 to serve as a guide to facilitate inserting the probe into the sheath (Col. 3, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a first panel extending beyond the second panel as taught by Poncy to facilitate insertion of the probe into the sheath.

8. Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Gammons et al (US 6224543) or Cianci in view of Barnes in view of Gammons. Claim

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6 differs from Cianci in calling for the cover to be partially inverted. Claim 18 differs from Cianci in view of Barnes in calling for the step of inverting the second end. Gammons teaches a sheath having a second end that has been inverted to facilitate movement of the sheath onto the tip of a medical probe (Col. 1, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to be partially inverted as taught by Gammons to facilitate movement of the sheath onto the tip of a medical probe.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Weaver (US 5667068). Claim 7 differs from Cianci in calling for the cover to be fabricated of a material having elastomeric properties. Weaver teaches a protective cover for a medical probe formed of an elastic material so that the cover can protect the delicate probe (Col. 2, lines 61-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to be formed of an elastic material as taught by Weaver to protect the delicate probe.

10. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Poncy and further in view of Wu. Cianci discloses a catheter sheath having a first panel member 48a and a second panel member 48b defining a tubular configuration, the first panel being folded over to form a double thickness, and the second panel being folded over to form a double thickness (Col. 3, lines 30-40). See Fig. 2.

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11. Claim 8 differs from Cianci in calling for the first panel member to extend beyond the second panel. Poncy teaches a cover having a first panel 24 that projects beyond the end of the second panel 22 to serve as a guide to facilitate inserting the probe into the sheath (Col. 3, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a first panel extending beyond the second panel as taught by Poncy to facilitate insertion of the probe into the sheath.

12. Claim 8 further differs from Cianci in view of Poncy in calling for the cover to further comprise a throat. Claim 9 differs in calling for the width of the throat to be less than one half of the circumference of the medical probe. Wu teaches a cover 10 for a medical probe having a throat 37 with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

13. Claim 10 differs from the teachings above in calling for the cover to have a funnel configuration. Poncy teaches a medical probe cover having a first end with a flaring or funnel configuration to facilitate the insertion of the medical probe (Col. 4, lines 18-22). See Fig. 5. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to have a first end with a funnel configuration as taught by Poncy to facilitate insertion of the probe.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Poncy in further view of Wu as applied to claim 8 above, and further in view of Gammons. Claim 11 differs from the teachings above in calling for the cover to be partially inverted. Gammons teaches a sheath having a second end that is inverted to facilitate movement of the sheath onto the tip of a medical probe (Col. 1, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to be partially inverted as taught by Gammons to facilitate movement of the sheath onto the tip of a medical probe.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Poncy in further view of Wu as applied to claim 8 above, and further in view of Weaver. Claim 12 differs from the teachings above in calling for the cover to be fabricated of a material having elastomeric properties. Weaver teaches a protective cover for a medical probe formed of an elastic material so that the cover can protect the delicate probe (Col. 2, lines 61-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to be formed of an elastic material as taught by Weaver to protect the delicate probe.

#### ***Response to Arguments***

16. Applicant's arguments filed 8/9/06 have been fully considered but they are not persuasive. Regarding claim 1, applicant argues that Cianci does not teach the folding of the



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panel members prior to securement. As stated in the above action, this is a product by process limitation, and thus does not give the claim patentability.

17. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the references is found in the teaching reference as discussed in the above action.

18. Applicant's arguments, see page 9, filed 8/9/06, with respect to the rejection(s) of claim(s) 13 under Cianci have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Cianci in view of Barnes.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125.

The examiner can normally be reached on Monday-Friday 8-4.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle  
Examiner  
Art Unit 3763

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